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EXAMINER

ART UNIT

PAPER NUMBER

DATE MAILED: 02/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



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EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO 90/007878

PATENT NO. 5,514,154

ART UNI 3900

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified ex parte reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the ex parte reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Order Granting / Denying Request For Ex Parte Reexamination	Control No. 90/007,878	Patent Under Reexamination 5515154	
	Examiner Sara S. Clarke	Art Unit 3993	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

The request for *ex parte* reexamination filed 17 January 2006 has been considered and a determination has been made. An identification of the claims, the references relied upon, and the rationale supporting the determination are attached.

Attachments: a) ☐ PTO-892, b) ☒ PTO-1449, c) ☐ Other: _____

1. ☒ The request for *ex parte* reexamination is GRANTED.

RESPONSE TIMES ARE SET AS FOLLOWS:

For Patent Owner's Statement (Optional): TWO MONTHS from the mailing date of this communication (37 CFR 1.530 (b)). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).**

For Requester's Reply (optional): TWO MONTHS from the **date of service** of any timely filed Patent Owner's Statement (37 CFR 1.535). **NO EXTENSION OF THIS TIME PERIOD IS PERMITTED.** If Patent Owner does not file a timely statement under 37 CFR 1.530(b), then no reply by requester is permitted.

2. ☐ The request for *ex parte* reexamination is DENIED.

This decision is not appealable (35 U.S.C. 303(c)). Requester may seek review by petition to the Commissioner under 37 CFR 1.181, within ONE MONTH from the mailing date of this communication (37 CFR 1.515(c)). **EXTENSION OF TIME TO FILE SUCH A PETITION UNDER 37 CFR 1.181 ARE AVAILABLE ONLY BY PETITION TO SUSPEND OR WAIVE THE REGULATIONS UNDER 37 CFR 1.183.**

In due course, a refund under 37 CFR 1.26 (c) will be made to requester:

- a) ☐ by Treasury check or,
b) ☐ by credit to Deposit Account No. _____, or
c) ☐ by credit to a credit card account, unless otherwise notified (35 U.S.C. 303(c)).

cc:Requester (if third party requester)

Control Number: 90/007,878
Art Unit 3993

Page 1

Decision on Request for Reexamination

A substantial new question of patentability ("SNQ") affecting claims 1, 4, and 12 of United States Patent Number 5,514,154 ("subject patent") is raised by the request for *ex parte* reexamination.

EP Patent Application Pub. No. 540,290

The request indicates that requester considers claims 1 and 4 obvious over EP Patent Application Pub. No. 540,290 (EP '290) to Advanced Cardiovascular Systems in view of U.S. Patent No. 4,922,905 to Strecker.

EP '290 is a new teaching, not previously considered nor addressed in the previous examination of the patent or a final holding of invalidity by the Federal Courts.

The subject patent matured from application 08/281,790, which is a continuation-in-part of parent application 08/164,986, which is a continuation (FWC) of application 07/783,558. The examiner in this proceeding has reviewed the file for applications 08/164,986 and 07/783,558 (the "parent applications") and has determined that the parent applications do not provide support for the following recitation in claim 1 of the subject patent: "a plurality of outwardly projecting edges which form as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter." Since there is no support for this recitation in the parent applications, claim 1 and the claims that depend thereon are not entitled to the benefit of the effective filing date of the parent applications.

EP '290 was published (May 5, 1993) more than one year prior to the filing date of application 08/281,790 (July 28, 1994). Since claims 1-11 are not entitled to the effective filing date of the parent applications, this reference is applicable against these

Control Number: 90/007,878
Art Unit 3993

Page 2

claims under 35 U.S.C. 102(b).

Claim 1 requires, *inter alia*, "a plurality of cylindrical elements which are independently expandable in the radial direction and which are interconnected so as to be generally aligned on a common longitudinal axis; [and] a plurality of connecting elements for interconnecting said cylindrical elements, said connecting elements configured to interconnect only said cylindrical elements that are adjacent to each other."

EP '290 discloses a plurality of cylindrical elements 12 which are independently expandable in the radial direction (col. 5, lines 7 and 8) and which are interconnected (col. 4, lines 35 and 36) so as to be generally aligned on a common longitudinal axis (claim 1); [and] a plurality of connecting elements 13 for interconnecting said cylindrical elements, said connecting elements configured to interconnect only said cylindrical elements that are adjacent to each other (Figs. 4 and 5, and col. 4, lines 3 and 36). Because EP '290 discloses cylindrical elements and a plurality of connecting elements as recited in claim 1, a reasonable examiner would have considered these references important in deciding whether or not the claim 1 of the subject patent is patentable.

U.S. Patent No. 5,102,417 to Palmaz, considered in the earlier concluded examination, also discloses cylindrical elements and a plurality of connecting elements as recited in claim 1. See page 2 of the office action dated March 28, 1994. However, EP '290 was not applied or discussed in the earlier concluded examination. Thus, it cannot be said that EP '290 raises the same question of patentability raised by the prior art previously considered in the earlier concluded examination. Therefore, EP '290 raises a SNQ with respect to claims 1 and 4.

Control Number: 90/007,878
Art Unit 3993

Page 3

U.S. Patent No. 4,922,905 to Strecker

The request indicates that requester considers claims 1 and 4 obvious over EP Patent Application Pub. No. 540,290 to Advanced Cardiovascular Systems in view of U.S. Patent No. 4,922,905 to Strecker.

Strecker is a new teaching, not previously considered nor addressed in the previous examination of the patent or a final holding of invalidity by the Federal Courts.

Claim 1 requires, *inter alia*, "an outer wall surface on said cylindrical elements, said outer wall surface being smooth prior to expansion of said stent and forming a plurality of outwardly projecting edges which form as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter."

Strecker discloses a stent whose outer wall surface is smooth prior to expansion See Fig. 8 and col. 9, lines 14-16. After the stent is expanded radially a plurality of outwardly projecting edges 36 form. See Fig. 9 and col. 9, lines 17 and 18.

Since Strecker provides the new teaching of projecting edges, which form as the stent is expanded radially, a reasonable examiner would consider this reference important in deciding whether or not to allow claim 1. Thus, Strecker raises a SNQ with respect to claims 1 and 4.

The Mirich Journal Article

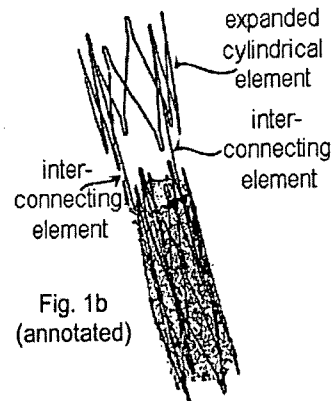
The request indicates that the requester considers claims 1 and 4 anticipated by the Mirich journal article. The request further indicates that the requester considers claims 1 and 4 obvious over the Mirich journal article (Embodiment of Fig. 1(a-c)) in view of the Rösch journal article or the Lawrence journal article.

Control Number: 90/007,878
Art Unit 3993

Page 4

The Mirich journal article is a new teaching, not previously considered nor addressed in the previous examination of the patent or a final holding of invalidity by the Federal Courts.

Figs. 1a-c of the Mirich journal article show a stent having a plurality of cylindrical elements. Fig. 1b shows the topmost cylindrical element independently expanded with respect to the bottommost cylindrical elements. As shown in Fig. 1b (as annotated by the examiner, at right), there are a plurality of interconnecting elements, which connect



only adjacent cylindrical elements. Since the Mirich journal article teaches independently expandable cylindrical elements and a plurality of interconnecting elements, which connect only adjacent cylindrical elements, a reasonable examiner would consider the teaching of the Mirich journal article important in deciding whether or not to allow claim 1 of the subject patent.

U.S. Patent No. 5,102,417 to Palmaz, considered in the earlier concluded examination, also discloses cylindrical elements and a plurality of connecting elements as recited in claim 1. See page 2 of the office action dated March 28, 1994. However, the Mirich journal article was not applied or discussed in the earlier concluded examination. Thus, it cannot be said that the Mirich journal article raises the same question of patentability raised by the prior art previously considered in the earlier concluded examination. Therefore, the Mirich journal article raises a SNQ with respect to claims 1 and 4.

Control Number: 90/007,878
Art Unit 3993

Page 5

The Rösch Journal Article

The request indicates that the requester considers claims 1 and 4 obvious over the Mirich journal article (Embodiment of Fig. 1(a-c)) in view of the Rösch journal article.

The Rösch journal article is a new teaching, not previously considered nor addressed in the previous examination of the patent or a final holding of invalidity by the Federal Courts.

The Rösch journal article at page 482, lines 31 and 32, discloses expansion of the cylindrical elements upon removal of the sheath. Figs. 2c and 2d show a plurality of outwardly projecting edges in the form of skirts.

Since the Rösch journal article provides the new teaching of an expandable stent having projecting edges, a reasonable examiner would consider this reference important in deciding whether or not to allow claim 1. Thus, the Rösch journal article raises a SNQ with respect to claims 1 and 4.

The Lawrence Journal Article

The request indicates that the requester considers claims 1 and 4 obvious over the Mirich journal article (Embodiment of Fig. 1(a-c)) in view of the Lawrence journal article.

The Lawrence journal article is a new teaching, not previously considered nor addressed in the previous examination of the patent or a final holding of invalidity by the Federal Courts.

The Lawrence journal article shows a plurality of outwardly projecting edges.
See Fig. 1b.

Since the Lawrence journal article provides the new teaching a stent having

Control Number: 90/007,878
Art Unit 3993

Page 6

projecting edges, a reasonable examiner would consider this reference important in deciding whether or not to allow claim 1. Thus, the Lawrence journal article raises a SNQ with respect to claims 1 and 4.

U.S. Patent No. 5,104,404 To Wolff

The request indicates that the requester considers claim 12 anticipated by U.S. Patent No. 5,104,404 to Wolff.

Wolff is listed on the information disclosure statement filed in parent application 07/783,558. As indicated by his initials next to the listing, the examiner considered Wolff in the parent application.

The following is a quotation from MPEP 609.02(A)(2): "The examiner will consider information which has been considered by the Office in a parent application when examining (A) a continuation application filed under 37 CFR 1.53(b) . . . or (C) a continuation-in-part application filed under 37 CFR 1.53(b)." Since the examiner considered Wolff in parent application 07/783,558, it is presumed that the examiner considered Wolff with respect to application 08/281,790.

On November 2, 2002, Public Law 107-273 was enacted. Title III, Subtitle A, Section 13105, part (a) of the Act revised the reexamination statute by adding the following new last sentence to 35 U.S.C. 303(a) and 312(a):

"The existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office."

For any reexamination ordered on or after November 2, 2002, the effective date of the statutory revision, reliance on previously cited/considered art, i.e., "old art," does not necessarily preclude the existence of a SNQ that is based exclusively on that old

Control Number: 90/007,878
Art Unit 3993

Page 7

art. Rather, determinations on whether a SNQ exists in such an instance shall be based upon a fact-specific inquiry done on a case-by-case basis.

Looking at the office actions of the examiner and the applicant's remarks in their responses, it can be seen that Wolff was not addressed in the examination of 08/281,790. Nor was it specifically addressed with regard to claim 12 of the subject patent. Moreover, Wolff was also not previously considered nor addressed in a final holding of invalidity by the Federal Courts. Therefore, the Wolff reference cannot be said to raise a question of patentability with respect to claim 12 raised in the earlier concluded examination or in a final holding of invalidity by the Federal Courts in a decision on the merits.

Claim 12 of the subject patent requires, "a plurality of cylindrical elements which are independently expandable in the radial direction and which are interconnected so as to be concentrically aligned on a common longitudinal axis; and a plurality of generally parallel connecting elements for interconnecting said cylindrical elements, said connecting elements configured to interconnect only said cylindrical elements that are adjacent to each other, so that said stent, when expanded radially outwardly, retains its overall length without appreciable shortening."

Wolff discloses a plurality of cylindrical elements 30 which are independently expandable in the radial direction (see Fig. 6) and which are interconnected so as to be concentrically aligned on a common longitudinal axis (See Fig. 4). Wolff also discloses a plurality of generally parallel connecting elements 32 for interconnecting said cylindrical elements. Connecting elements 32 interconnect only said cylindrical elements that are adjacent to each other. Finally, Wolff shows connecting elements

Control Number: 90/007,878
Art Unit 3993

Page 8

interconnecting only at peaks and valleys of the cylindrical elements. As noted by the requester, this is the only structure disclosed in the subject patent for allowing the stent to retain its overall length when expanded radially without appreciable shortening.

Since Wolff provides the teaching of a stent having (a) independently expandable cylindrical elements, which are interconnected and concentrically aligned along an axis, (b) a plurality of parallel connecting elements, which interconnect only adjacent cylindrical elements, and (c) connecting elements interconnecting only at peaks and valleys of the cylindrical elements, a reasonable examiner would consider this reference important in deciding whether or not to allow claim 12. Thus, Wolff raises a SNQ with respect to claim 12.

The Furui Journal Article

The request indicates that the requester considers claim 12 anticipated by the Furui journal article.

The Furui journal article is a new teaching, not previously considered nor addressed in the previous examination of the patent or a final holding of invalidity by the Federal Courts.

The Furui journal article shows a plurality of cylindrical elements interconnected so as to be concentrically aligned on a common longitudinal axis. See Fig. 1. The struts, which interconnect the cylindrical elements and are shown in Fig. 1, appear to be parallel to one another. The struts interconnect only adjacent cylindrical elements. Finally, Furui shows connecting elements interconnecting only at peaks and valleys of the cylindrical elements. As noted by the requester, this is the only structure disclosed in the subject patent for allowing the stent to retain its overall length when expanded

Control Number: 90/007,878
Art Unit 3993

Page 9

radially without appreciable shortening.

U.S. Patent No. 5,102,417 to Palmaz, considered in the earlier concluded examination, also discloses (a) expandable cylindrical elements, which are interconnected and concentrically aligned along an axis, (b) a plurality of parallel connecting elements, which interconnect only adjacent cylindrical elements, and (c) connecting elements interconnecting only at peaks and valleys of the cylindrical elements. See Figs. 7 and 10. However, the Furui was not applied or discussed in the earlier concluded examination. Thus, it cannot be said that Furui raises the same question of patentability raised by the prior art previously considered in the earlier concluded examination. Therefore, Furui raises a SNQ with respect to claim 12.

U.S. Patent No. 5,133,732 to Wiktor

The request indicates that the requester considers claim 12 anticipated by U.S. Patent No. 5,133,732 to Wiktor:

Like Wolff above, Wiktor is listed on the information disclosure statement filed in parent application 07/783,558. As indicated by his initials next to the listing, the examiner considered Wiktor in the parent application. Since the examiner considered Wiktor in parent application 07/783,558, it is presumed that the examiner considered Wiktor with respect to application 08/281,790.

Looking at the office actions of the examiner and the applicant's remarks in their responses, it can be seen that Wiktor was not addressed in the examination of 08/281,790. Nor was it specifically addressed with regard to claim 12 of the subject patent. Moreover, Wiktor was also not previously considered nor addressed in a final holding of invalidity by the Federal Courts. Therefore, the Wiktor reference cannot be

Control Number: 90/007,878
Art Unit 3993

Page 10

said to raise a question of patentability with respect to claim 12 raised in the earlier concluded examination or in a final holding of invalidity by the Federal Courts in a decision on the merits.

Wiktor discloses a plurality of cylindrical elements. See Fig. 8 at right (annotated). The arrows show where the elements end.

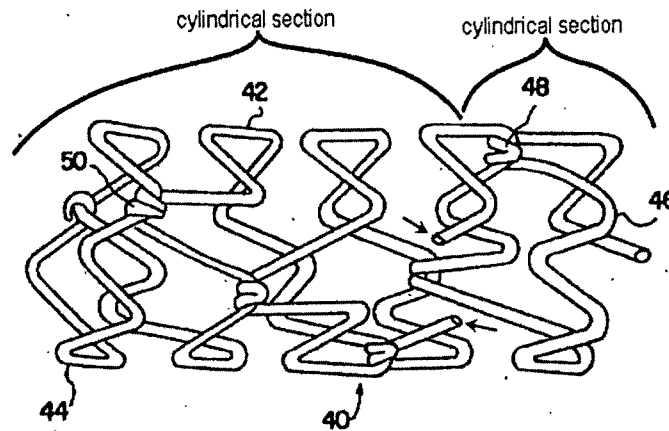


FIG. 8

Since Wiktor provides the teaching of a stent having a plurality of cylindrical elements, a reasonable examiner would consider this reference important in deciding whether or not to allow claim 12. Thus, Wiktor raises a SNQ with respect to claim 12.

Conclusion

For the reasons given above, the references cited by the requester raise a SNQ with respect to the subject patent. Accordingly, all of claims 1-23 of the subject patent will be reexamined.

Extensions of time under 37 CFR 1.136(a) will **not** be permitted in these proceedings because the provisions of 37 CFR 1.136 apply only to "an applicant" and not to parties in a reexamination proceeding. Additionally, 35 U.S.C. 305 requires that *ex parte* reexamination proceedings "will be conducted with special dispatch" (37 CFR 1.550(a)). Extensions of time in *ex parte* reexamination proceedings are provided for in 37 CFR 1.550(c).

The patent owner is reminded of the continuing responsibility under 37 CFR

Control Number: 90/007,878
Art Unit 3993

Page 11

1.565(a) to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving Patent No. 5,514,154 throughout the course of this reexamination proceeding. The third party requester is also reminded of the ability to similarly apprise the Office of any such activity or proceeding throughout the course of this reexamination proceeding. See MPEP §§ 2207, 2282 and 2286.

The patent owner is notified that any proposed amendment to the specification and/or claims in this reexamination proceeding **MUST** comply with 37 CFR 1.530(d)-(j), 37 CFR 1.52(a) and (b), and 37 CFR 1.20(c).

Contact Information

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Alexandria, VA 22314

Control Number: 90/007,878
Art Unit 3993

Page 12

Any inquiry concerning this communication or earlier communications from the Reexamination Legal Advisor or Examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.

Signed:



Sara Clarke
Primary Examiner
Central Reexamination Unit
(571) 272-4873

MB
AK